GENTLE LAXATIVE- bisacodyl tablet, delayed release CVS Pharmacy

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CVS 44-327

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

if you cannot swallow without chewing.

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

When using this product

- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk
- you may have stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative.
 These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

take with a glass of water

adults and children 12 years and	take 1 to 3 tablets in a single daily
over	dose
children 6 to under 12 years	take 1 tablet in a single daily dose
children under 6 years	ask a doctor

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- see end flap for expiration date and lot number

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-426-9391

Principal Display Panel

♥ CVS Health™

Compare to the active ingredient in Dulcolax® Laxative Tablets*

Gentle Laxative BISACODYL USP 5 mg

Stimulant Laxative

Gentle, dependable constipation relief

10 TABLETS (Enteric Coated)

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Sanofi-Aventis Deutschland GMBH, owner

of the registered trademark Dulcolax® Laxative Tablets. 50844 REV0119B32703

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V-14236

OVERNIGHT RELIEF

♥CVSHealth。

Gentle

BISACODYL USP 5 mg Stimulant Laxative



Compare to the active ingredient in Dulcolax® Laxative Tablets*

Gentle

_axative

BISACODYL USP 5 mg Stimulant Laxative

Gentle, dependable constipation relief



(Enteric Coated)



Actual Size

polydextrose, polyethylene glycol, polyvinyl acetate anhydrous, magnesium stearate, methylparaben, lake, hypromellose, iron oxide black, lactose #10 aluminum lake, FD&C yellow #6 aluminum colloidal anhydrous silica, com starch, D&C yellow

nund racts (continued)

B-0231-327-03-H REV0119B32703

#317857

: CVS Pharmacy, Inc. Woonsocket, RI 02895

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2

xpiration No.

No Varnish

triethyl citrate stearic acid, sucrose, talc, titanium dioxide, triacetin,

alginate, sodium benzoate, sodium bicarbonate, propylparaben, shellac glaze, simethicone, sodium

Drug Facts (continued)

hydroxide, calcium carbonate, carnauba wax,

■ see end flap for expiration date and lot number ■ svoid excessive humidity

INACTIVE INGYECTIENTS acacia, ammonium

- Detween 15°-30°C (59°-86°F)
- store at 25°C (77°F); excursions permitted OB BBOKEN

PACKAGE IS OPENED OR BLISTER IS TORN ■ TAMPER EVIDENT: DO NOT USE IF OUTER Other information

	sak a doctor	children under 6 years
ľ	single daily dose	12 years
l.	take 1 tablet in a	children 6 to under
ľ	in a single daily dose	12 years and over
l	take 1 to 3 tablets	
l	th a glass of water	Directions = take wi

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and cramps

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When using this product

more than 2 weeks

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cuewing.

Do not use if you cannot swallow without Marnings

movement in 6 to 12 hours πιιο μισιατός βειμείαμή μισιατός ποιμεί

Drug Facts (continued -800-426-9391

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CVS 44-327

GENTLE LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-327

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) BISACODYL 5 mg

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B710)	
DIMETHICONE (UNII: 92RU3N3Y10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics					
Color orange Score no score					
Shape	ROUND	Size	6mm		
Flavor		Imprint Code	5		
Contains					

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779- 327-03	1 in 1 CARTON	03/25/2002	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779- 327-15	2 in 1 CARTON	03/25/2002	
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:59779- 327-56	1 in 1 CARTON	03/25/2002	
3		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:59779- 327-33	7 in 1 CARTON	03/25/2002	
4		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	03/25/2002		

Labeler - CVS Pharmacy (062312574)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-327)
ENC meernadonal, me.		030131101	pack(33773 327)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(59779-327)	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(59779-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(59779-327)

Revised: 11/2021 CVS Pharmacy